Discussion of the Rejection Under 35 U.S.C. § 112, first paragraph

The Office has rejected claims 1-3, 22, 24 and 26 as allegedly lacking enablement under Section 112, first paragraph. This rejection is traversed for the reasons set forth below.

According to the Office, "the specification, while being enabling for treating the specific cancer ... does not reasonably provide enablement for the term 'a cancer' and 'a genetic defect of a cancer regulatory gene or a tumor suppressor gene.'" The Office reasons that "the treatment of cancer art remain [sic] highly unpredictable, and no examples exist for efficacy of a single product against all types of claimed conditions or diseases generally." However, contrary to the Office's contention, independent claim 1, and the claims dependent thereon, are directed to "a method for the prophylactic or therapeutic treatment of cancer in an animal ... wherein said cancer is susceptible to prevention or treatment by said nitroxide or prodrug thereof." In other words, claim 1 is not directed to the treatment of all cancers, as characterized by the Office, but rather is directed to only those cancers susceptible to prevention or treatment by nitroxides, or prodrugs thereof.

In addition, Applicants need not exemplify each and every embodiment of the claimed invention. Applicants need only teach those of ordinary skill in the art how to make and use the present invention. In this regard, Applicants point out that Examples I and II of the instant specification describe the *in vivo* efficacy of nitroxides to treat cancers susceptible to prevention or treatment by nitroxides. Other exemplary cancers that are susceptible to prevention or treatment by the nitroxides, or prodrugs thereof, encompassed within the scope of the present invention, are described in the specification at, for example, page 6, lines 12-29. Nitroxides are described in the specification at, for example, page 7, line 24, to page 10, line 14. Chemical synthesis of nitroxides is described in the specification at, for example, page 11, lines 12-26. Suitable doses are described in the specification at, for example, page 10, line 27, to page 11, line 11. Formulations of nitroxides are described in the specification at, for example, page 12, line 8, to page 15, line 12, and includes modes of administration, carriers, and concentrations. Therefore, no undue experimentation would be required for one of ordinary skill in the art to practice the method of the present invention. Accordingly, claims 1-3, 22, 24 and 26 are enabled by the specification and this rejection should be withdrawn.

Discussion of the Rejection Under 35 U.S.C. § 102(b)

The Office has rejected claims 1-3 under Section 102(b) as allegedly being anticipated by Monti I. This rejection is traversed for the reasons set forth below.

Monti I does not teach and, therefore, does not enable, a method of using a nitroxide, or a prodrug thereof, to treat cancer in an animal prophylactically or therapeutically. Therefore, Monti I cannot be said to anticipate the present invention.

The Office's citation of *Novitski* does not support its position. *Novitski* is directed to a situation in which the primary reference that was being cited by an Examiner as a basis for an obviousness rejection disclosed every element of the claimed method. The primary reference, however, did not expressly disclose an inherent property of the active agent. Secondary references were cited to provide the teaching of the inherent property. Upon appeal to the Board of Patent Appeals and Interferences, the obviousness rejection was withdrawn in favor of an anticipation rejection in view of the primary reference. *Novitski*, thus, is directed to inherent anticipation.

The case at hand can be distinguished from *Novitski*. As indicated above, the sole reference cited as a basis for rejection, namely Monti I, does not teach and, therefore, does not enable, a method of treating an animal, let alone a method of using a nitroxide, or a prodrug thereof, to treat cancer in an animal prophylactically or therapeutically as taught by the present invention.

In view of the above, the rejection of claims 1-3 under Section 102(b) cannot stand. Accordingly, Applicants request the withdrawal of this rejection.

Discussion of the Rejection Under 35 U.S.C. § 103(a)

The Office has rejected claims 24-27 under Section 103(a) as allegedly being obvious in view of and, therefore, unpatentable over Monti II in view of Harris. This rejection is traversed for the reasons set forth below.

The Office admits that Monti II differs from the claimed invention because Monti II is directed to the cytotoxicity of Tempol on human leukemic cell lines *in vitro*. The Office alleges, however, that one of ordinary skill in the art would have been motivated to modify the teachings of Monti II such that Tempol is administered to an animal, including an animal with a p53 mutation in view of Harris, to treat cancer. The Office further alleges that the ordinarily skilled artisan would have had a reasonable expectation of success in doing so.

Monti II does not teach or suggest, and certainly does not enable, a method of using a nitroxide, or a prodrug thereof, to treat cancer in an animal prophylactically or therapeutically. Harris does not cure the deficiencies of Monti II. Like Monti II, Harris does not teach or suggest, and certainly does not enable, a method of using a nitroxide, or prodrug thereof, as claimed. Neither reference teaches doses, formulations, modes of administration, carriers and concentrations with respect to the use of a nitroxide in the prophylactic and

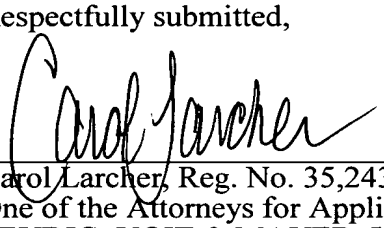
therapeutic treatment of cancer as taught by the present invention. In the absence of such a teaching or suggestion, Monti II in view of Harris cannot be said to render the present invention obvious. One of ordinary skill in the art would not have been motivated to combine the references as suggested by the Office and even if, for the sake of argument, one of ordinary skill in the art would have been motivated to combine the references, the ordinarily skilled artisan would not have arrived at a method of treating cancer in an animal prophylactically or therapeutically in accordance with the present invention. In addition, one of ordinary skill in the art would not have had a reasonable expectation, based on an *in vitro* showing of Tempol inducing apoptosis in leukemic cell lines, of success *in vivo*.

In view of the above, Applicants submit that claims 24-27 are not obvious in view of the cited references. Accordingly, Applicants request the withdrawal of this rejection.

Conclusion

The application is considered to be in good and proper form for allowance, and the Examiner is respectfully requested to pass this application to issue. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned attorney.

Respectfully submitted,



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Date: May 1, 2001

In re Appln. of Mitchell et al.
Application No. 09/424,519

CERTIFICATE OF MAILING

I hereby certify that this RESPONSE TO OFFICE ACTION (along with any documents referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date shown below with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, Washington, D.C. 20231.

Date: May 1, 2001 Ellen K. Marcus

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